UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----------X

ELIZABETH WEBB,

Plaintiff,

-against-

ZIMMER, INC., ZIMMER HOLDINGS, INC., and ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC.,

Defendants.

----------X

MEMORANDUM OF DECISION & ORDER
2:14-cv-01106 (ADS)(GRB)

APPEARANCES:

Silverson Pareres & Lombardi LLP
Counsel for the Plaintiff
192 Lexington Avenue, 17th Floor
New York, NY 10016
By: Nancy Maltin, Esq.,
Joseph Pareres, Esq., Of Counsel

McCarter & English LLP
Co-Counsel for the Defendants
245 Park Avenue, 27th Floor
New York, NY 10167
By: Minji Kim, Esq.,
Zane Riester, Esq., Of Counsel

Faegre Baker Daniels LLP
Co-Counsel for the Defendants
110 West Berry Street, Suite 2400
Fort Wayne, Indiana 46802
By: Peter Meyer, Esq.,
Joseph Price, Esq., Of Counsel

SPATT, District Judge:

On February 20, 2014, Elizabeth Webb (the "Plaintiff" or "Webb") initiated this product liability action against, Zimmer, Inc. ("Zimmer" or the "Defendant"), Zimmer Holdings, Inc., and Zimmer Orthopedic Surgical Products, Inc. (together with Zimmer, the "Defendants") in this Court. Presently before the Court is a renewed motion for summary judgment filed by the Defendants on July 16, 2018, pursuant to Federal Rule of Civil Procedure ("FED. R. CIV. P." or "Rule") 56, and a motion to strike the affidavit of Douglas B. Unis, M.D. filed by the Defendants on July 2, 2018, pursuant to Federal Rule of Evidence ("FED. R. EVID.") 702.

Prior to its ruling, the Court notes that the Plaintiff's memorandum does not conform to this Court's Individual Rule IV.B ("Unless prior permission has been granted, memoranda of law in support of and in opposition to motions are limited to 25 pages … Memoranda of 10 pages or more shall contain a table of contents."), as it fails to include a table of contents and exceeds 25 pages. The Court advises the Plaintiff's counsel to conform to this Court's Individual Rules in the future. Any subsequent motions filed with this Court that do not comply with its Individual Rules will be rejected. *See Id*. ("Motions not in conformity with the rules set forth herein will be returned to the movant undocketed or disregarded.").

For the reasons set forth herein, the Defendants' motion to strike is granted and the motion for summary judgment pursuant to Rule 56 is granted.

I. BACKGROUND

A. THE FACTUAL BACKGROUND

1. The Plaintiff & the First Surgery

The Plaintiff was born on May 10, 1955 and is currently 63 years old. She was approximately 5'3" tall and weighed approximately 150 pounds with a body mass index of 28

during the relevant time period. Rule 56.1(b) Statement of Undisputed Facts ("56.1 Statement") ¶ 3. On January 1, 2011, in response to pain in her right knee, she saw Dr. Norman Scott, an orthopedic surgeon. He ordered an MRI, which revealed arthritis in the right knee, medial and lateral meniscal tears, and noted an abnormal ACL with signs consistent with a torn ligament. *Id*.

In February 2011, Webb visited Dr. Douglas Unis for the first time. Dr. Unis is an orthopedic surgeon who was referred to Webb by Dr. Ramon Tallaj. X-rays "confirmed that she had a severely arthritic right knee with actually about a 15-degree 'varus' deformity." *Id*. ¶ 4. On March 14, 2011, Dr. Unis performed a right total knee replacement on Webb using a Zimmer Gender Solutions Natural-Knee Flex System (the "Product"). The Product included (1) a Zimmer Gender Solutions Natural-Knee Flex Femoral Component; (2) a Zimmer Gender Solutions Natural-Knee Flex Prolong Ultracongruent Articular Surface; (3) a Zimmer Gender Solutions Natural-Knee II Nonporous Tibial Baseplate; and (4) a NexGen All-Polyethylene Patellar component. *Id*. ¶ 5. The Product relies on a combination of cemented and uncemented components known as "hybrid" fixation. The femoral component depends on bone growth into the pores of the implant's surface and the tibial and patellar components were secured using bone cement. The operative report indicates that Dr. Unis encountered no complications or issues during the surgery. *Id*. At the time of her surgery, the Plaintiff was 55 years old.

Between 2011 and 2014, Dr. Unis performed between 150 and 200 knee replacements a year. Approximately 85 percent of those were primary total knee replacements. *Id*. ¶ 73. At the time, Dr. Unis was using the Product for all of his primary knee replacements, regardless of the specifics of his patients' conditions. Docket Entry ("DE") 63-4 at 44:18-22. He "was comfortable with the nuances of the system which [he believes] contributes to the success of putting in an implant." *Id*. at 44:22-25. In his opinion, "you are better off having the surgeon be comfortable

with whatever system that he or she uses than having that surgeon use whatever is the latest, greatest thing being marketed." *Id*. at 45:6-10. Dr. Unis continued to use the Product in his primary knee replacements through 2014 and remained comfortable with the Product at that time. 56.1 Statement ¶ 74.

He testified that 20 percent of total knee replacements will require revision surgery within 20 years after they are implanted. *Id*. ¶ 78.

2. Post-Operative

Ten days after her surgery, Dr. Unis remarked that Webb "really looked great. She is using a cane. She has got full extension, flexion to 105 degrees even." *Id*. ¶ 6. On April 18, 2011, the Plaintiff attended her first outpatient physical therapy appointment, where she described her pain as intermittent and worse with prolonged ambulation and weight-bearing. She also complained of "weakness of [her] quads." *Id*. ¶ 7. The physical therapist prescribed a four-week course of rehabilitation using 12 sessions. The Plaintiff only completed four out of the 12 prescribed sessions. *Id*.

On April 21, 2011, Dr. Unis observed that "[s]he looks absolutely beautiful. She has full extension, flexion to 120 degrees. No pain. No instability." *Id*. ¶ 8. That June, Dr. Unis reported again that "[s]he looks fantastic." *Id*. ¶ 9.

On August 18, 2012, the Plaintiff was seen at the emergency room of St. Luke's-Roosevelt Hospital Center, where she was complaining of knee pain. She claims that she "[heard a] popping/cracking noise while walking yesterday" and was "unable to bear weight [on it]." There was no evidence in an x-ray of "interval hardware loosening or failure," but there was "interval development of a large suprapatellar joint effusion [and] mild associated posterior subluxation of the femur with respect to the tibial plateau." *Id*. ¶ 10. Later that day, Dr. Unis performed a revision

surgery. During the surgery, Dr. Unis identified and removed "the anteriorly dislocated polyethylene spacer." He also found a "broken locking mechanism piece of polyethylene." Dr. Unis inserted another 16-mm thick Zimmer Gender Solutions Natural-Knee Flex Prolong Ultracongruent Tibial Articular Surface, which was the same thickness originally implanted in Webb. *Id*. ¶¶ 11-12.

On November 8, 2012, Webb informed Dr. Unis during a post-operative visit that she "was basically back to normal until about 2 weeks ago when she started feeling some giving way of the knee and some particularly lateral and anterior knee pain." Dr. Unis also reported that her "stability is good" and that "she actually has firm endpoints at full extension as well as 20 degrees of flexion similar to what she had prior to the implant failure." *Id*. ¶ 14. X-rays reported that "there may be some posterior subluxation of the femoral head with respect to the tibial plateau." *Id*. ¶ 15.

On November 24, 2012, Webb again went to the hospital complaining of pain in her right knee. *Id*. ¶ 16. Two days later, Dr. Unis performed a second revisionary surgery to replace the dislocated Natural-Knee Flex Prolong Ultracongruent Tibial Articular Surface. However, there was no breakage or other deformities observed on either the Natural-Knee II Nonporous Tibial Baseplate or the Articular Surface. *Id*. ¶ 17. This time, a thicker replacement part was used, one with a thickness of 19 mm. *Id*. ¶ 19. She was released from the hospital on November 27, 2012. *Id*. ¶ 18. On December 7, 2012, Webb reported to Dr. Unis during a visit that "the knee is feeling quite secured and [she] is very happy with her progress." *Id*. ¶ 21.

In October 2013, Webb visited two other orthopedic surgeons to obtain second and third opinions regarding her knee pain. She reported "having knee pain and feel[ing] the same antecedent symptoms that she was having last time she dislocated." *Id*. ¶¶ 21-22. On October 25, 2013, Webb saw Dr. Unis claiming, "feelings of instability similar to what she felt prior to poly

failure last year." Dr. Unis suggested that using a more constrained, "revision type knee" was the most prudent course of action, given her recurrent issues of instability. *Id*. ¶ 23.

On September 30, 2014, Webb yet again complained that she had "an exacerbation [in] feelings of instability in the right knee over the past 2 weeks." The Plaintiff and Dr. Unis determined that a more constrained total knee replacement device was appropriate for her. *Id*. ¶ 24.

On October 13, 2014, Dr. Uris performed a full revision surgery on Webb's right knee that replaced the Product with a constrained total knee replacement system. This system contained a Zimmer Legacy-Knee Constrained Condylar Knee Femoral Component ("Replacement Product"), a NexGen Stemmed Tibial Component, and a LCCK Articular Surface. Dr. Unis observed no loosening, dislocation, or breakage of any of the Product's components. *Id*. ¶ 25. Webb was released from the hospital on October 15, 2014. *Id*. ¶ 26.

On March 19, 2015, Dr. Unis noted in a post-operative visit that Webb was "doing beautifully and feeling like her knee is stable." *Id*. ¶ 27. The Plaintiff has done well with her total knee replacement after switching to the more constrained Replacement Product. *Id*.

3. Design and Labeling of the Product

When the Product was designed, Zimmer performed two series of tests to assess the durability of the articular surface locking mechanisms: (1) Anterior-Posterior Shear Fatigue Testing of the N-K Flex Prolong Articular Surface to gauge the durability of the locking mechanism against anterior and posterior shear forces; and (2) Anterior Liftoff Testing of the N-K Flex Prolong Articular Surfaces to evaluate the resistance of the locking mechanism to anterior liftoff. *Id*. ¶ 39. In addition, Zimmer completed functional relationship layouts during the design process to confirm that the GS-NKF femoral components did not impinge on the posterior

eminence of the articular surface at up to 15 degrees of hyperextension. *Id*. ¶ 47. When Zimmer modified the articular surface, it repeated the anterior liftoff testing of that component in the Product. *Id*. ¶ 46.

Webb's first two N-K Flex Articular Surfaces contained Packaged Inserts with a list of the indications, warnings, risks, contraindications, adverse effects, precautions, and patient counseling information for the Product. *Id*. ¶ 48. In the Package Inserts, under "Adverse Effects," the surgeon is warned of, in pertinent part: (1) "Loosening or fracture/damage of the prosthetic knee components or surrounding tissues;" (2) "Dislocation and/or joint instability;" and (3) "Pain." *Id*. ¶ 49. In the "Warnings" section, the surgeon is informed that "[s]oft [t]issues should be balanced and components positioning confirmed to minimize edge loading." *Id*. ¶ 50. Under "Patient Counseling Information," the insert states that "[b]ecause prosthetic joints are not as strong, reliable, or durable as natural, healthy joints, all prosthetic knees may need to be replaced at some point." *Id*. ¶ 51. The Surgical Technique Guide also warns that surgeons need to "[a]void excessive posterior slope especially if the posterior cruciate ligament is deficient." *Id*. ¶ 52.

B. THE PROCEDURAL BACKGROUND

On February 20, 2014, Webb filed this action against the Defendants, alleging that the Product, in particular the Zimmer Gender Solutions Natural-Knee Flex Prolong Ultracongruent Articular Surface, is defective. *Id*. ¶ 1. At this point in time, Webb has abandoned design defect claims and confined her claims to those based on a failure-to-warn theory. *Id*. ¶ 2.

On November 30, 2016, fact and expert discovery was completed in this matter. *See* DE 40. As part of expert discovery, Dr. Douglas Unis was deposed on August 25, 2015.

On January 17, 2017, the Defendants filed a motion to exclude the testimony of one of the Plaintiff's experts, Mari Truman. *See* DE 44. In the Plaintiff's opposition papers, Webb included

an Affidavit from Dr. Douglas Unis, dated February 17, 2017 (the "Unis Affidavit" or the "Affidavit"). *See* DE 49-7. On February 27, 2017, the Defendants filed a motion to strike the Unis Affidavit. *See* DE 52.

This Court held a pre-motion conference on March 29, 2017 and denied the Defendants' motion to exclude Truman's expert testimony. *See* DE 57-58. The Court further noted that the Defendants' motion to strike the Unis Affidavit was denied as moot. *Id*.

On June 28, 2017, the Defendants filed their first motion for summary judgment pursuant to Rule 56. *See* DE 64. In the Plaintiff's opposition papers, which were filed on August 22, 2017, Webb once again included the Unis Affidavit. *See* DE 78-4. This prompted the Defendants to reintroduce the motion to strike the Affidavit, which was filed on September 7, 2017. *See* DE 80.

On February 12, 2018, the Court issued a memorandum of decision & order granting-in-part the Defendants' motion to strike to the following extent: (1) the Court reopened discovery for the purpose of allowing the Defendants to re-depose Dr. Unis; (2) the law firm of Silverson Pareres & Lombardi was ordered to pay the Defendants' attorney's fees associated with the renewed deposition of Dr. Unis; and (3) Silverson Pareres & Lombardi was further ordered to pay the Defendants' reasonable attorney's fees incurred in bringing the renewed motion to strike. Further, the Defendants' first motion for summary judgment was denied without prejudice with leave to renew at the close of the additional discovery period.

On April 12, 2018, counsel for the Defendants re-deposed Dr. Unis. During this deposition, Dr. Unis testified that the Plaintiff's attorneys wrote the Affidavit and that he signed it without making any changes. Declaration of Peter A. Meyer ("Meyer Decl."), DE 94, Ex. B at 51:4-53:10. Dr. Unis acknowledged that he did not review Truman's expert report, the package insert, or the

surgical technique guide prior to signing the Affidavit. *Id*. at 12:8-14:21. At his second deposition, Dr. Unis confirmed that the Affidavit contained inaccuracies, errors, and imprecise language.

On July 2, 2018, the Defendants filed a motion to exclude the expert testimony of Dr. Unis. Two weeks later, they filed a renewed motion for summary judgment. These motions were fully briefed on September 5, 2018.

II. THE MOTION TO STRIKE

A. STANDARD OF REVIEW

The Defendants seek to exclude the testimony of Dr. Brian Unis on the basis that the opinions expressed in the Affidavit do not meet the standards for admissibility outlined in *Daubert* and its progeny. In other words, the Defendants allege that the Unis Affidavit is a "sham affidavit."

Prior to the Supreme Court's interpretation of FED. R. EVID. 702 in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), the test to determine if scientific evidence was admissible at trial was whether the evidence was "generally accepted" as reliable within the relevant scientific community. *See Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). The *Frye* standard allowed novel scientific evidence to be admitted only if it was based on a generally accepted method or theory. *Frye*, 293 F. at 1014. *Daubert*, however, held that the *Frye* test was superseded by the adoption of the Federal Rules of Evidence, which included a liberal relevance standard. FED. R. EVID. 401 states that evidence is relevant if it has any tendency to make the existence of any fact of consequence to the action more or less probable. FED. R. EVID. 401.

FED. R. EVID. 702, entitled "Testimony by Experts," states that: "[i]f … scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue," "a witness who is qualified as an expert by knowledge, skill,

experience, training, or education, may testify thereto in the form of an opinion or otherwise." FED. R. EVID. 702. Examining FED. R. EVID. 702, *Daubert* provides a flexible analysis to guide trial courts in determining whether proffered submissions of scientific evidence are admissible. The Supreme Court emphasized the "flexibility" that should guide the trial court when making a determination of the admissibility of scientific evidence and stressed that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 595 (internal citations omitted). *But cf. Amorgianos v. Nat'l P.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002) ("A minor flaw in an expert's reasoning or a slight modification of an otherwise reliable method will not render an expert's opinion per se inadmissible. 'The judge should only exclude the evidence if the flaw is large enough that the expert lacks good grounds for his or her conclusions.'" (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 746 (3d Cir. 1994))).

When faced with the prospect of expert testimony:

> the trial judge must determine at the outset, pursuant to Rule 104(a) whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Daubert, 509 U.S. at 592–93 (internal citations omitted). The Supreme Court provided a list of factors for a trial court to consider when making this determination, but emphasized that "we do not presume to set out a definitive checklist or test." *Id*. at 593. The four factors include: (1) whether the theory or technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error in the case of a particular scientific technique; and (4) whether the theory or technique is generally accepted

within the relevant scientific community. *Id*.; *see generally Zuchowicz v. United States*, 140 F.3d 381 (2d Cir. 1998); *Iacobelli Constr., Inc. v. Cty. of Monroe*, 32 F.3d 19 (2d Cir. 1994). These factors are not considered exhaustive and the Supreme Court noted that other relevant factors may be reviewed. *Daubert*, 509 U.S. at 593.

Other factors include: (1) whether the proposed expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field," *Kumho Tire Co.. v. Carmichael*, 526 U.S. 137, 152, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999); (2) whether the expert's field lacks reliability, *Id*. at 151; (3) whether the testimony comes from research conducted independent of litigation, *see Daubert v. Merrell Dow Pharm.*, 43 F.3d 1311, 1317 (9th Cir. 1995); (4) whether the proposed expert has considered additional explanations in his analysis, *see Ambrosini v. Labarraque*, 101 F.3d 129, 140 (D.C. Cir. 1996); and (5) the "non-judicial uses to which the scientific technique are put." *United States v. Downing*, 753 F.2d 1224, 1239 (3d Cir. 1985).

While the four guidelines enunciated in *Daubert* "leave in place the 'gatekeeper' role of the trial judge in screening such evidence," *General Elec. Co. v. Joiner*, 522 U.S. 136, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997), the Second Circuit in *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038 (2d Cir. 1995) held that:

> [t]rial Judges must exercise sound discretion as gatekeepers of expert testimony under *Daubert*. [The Appellant], however, would elevate them to the role of St. Peter at the gates of heaven, performing a searching inquiry into the depth of the expert witness's soul—separating the saved from the damned. Such an inquiry would inexorably lead to evaluating witness credibility and weight of evidence, the ageless role of the jury.

Id. at 1045.

In sum, the Federal Rules of Evidence, the Supreme Court's decision in *Daubert*, and the principles and guidance of the Second Circuit require this Court, when making a decision as to

whether to admit expert testimony to: (1) determine whether the witness is qualified to testify as an expert by examining the witnesses educational or experiential qualifications in the relevant field; and (2) using the non-exhaustive factors enunciated as guidelines, determine whether the proposed testimony will involve the relevant specialized knowledge that will assist the trier of fact to understand or to determine a fact in issue. While the focus of the Court's inquiry must remain on the methodology rather than the conclusions, the Court is not obligated to accept conclusions that do not flow from the facts and methodologies used. *Amorgianos*, 303 F.3d at 266 (internal citations omitted).

Following *Daubert*, it has become a well-accepted principle that FED. R. EVID. 702 is to be interpreted in a liberal standard of admissibility, which is a departure from the more restrictive *Frye* standards. *See Nimely v. City of New York*, 414 F.3d 381, 395 (2d Cir. 2005). However, despite a more permissive approach to expert testimony, the Court must ensure that "any and all scientific (or other expert) testimony or evidence admitted is not only relevant but reliable." *Daubert*, 509 U.S. at 589.

Six years after *Daubert*, in *Kumho Tire Co.*, 526 U.S. at 152, the Supreme Court further clarified that, whether a witness's area of expertise was technical, scientific, or more generally "experience-based," FED. R. EVID. 702 required the district court to fulfill the "gatekeeping" function of "mak[ing] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id*.

Also, as stated above, the requirement of "reliability" is extremely important and requires a clear analytical connection between the expert's methodology and his conclusions. So that *Daubert* and FED. R. EVID. 702 "mandate the exclusion of ... unreliable opinion testimony."

Amorgianos, 303 F.3d at 266. The Supreme Court assigned to the trial judge the task of ensuring that an expert's testimony rests on a reliable foundation and is relevant to the issues in the case. Further, the trial judge has latitude in deciding how to test an expert's reliability and whether the expert's relevant testimony is reliable.

It is within this framework that the Court will exercise its gatekeeper role and address this motion by the Defendants to exclude the testimony of Dr. Unis.

B. ANALYSIS

The Defendants allege that the Unis Affidavit contains facts and opinions that he disagrees with and/or that he agrees that he lacks the reliable data to support. Specifically, the Defendants point to the following opinions as excludable:

> (1) That Zimmer's testing for the Gender Solutions Natural-Knee Flex (the "N-K Flex") was inadequate because it was allegedly not tested for patients with hyperextension or high posterior tibial slope, and that Zimmer should have disclosed this to surgeons ([Meyer Dec. Ex. A], ¶ 7);
>
> (2) That Zimmer should have included a warning or contraindication for patients with hyperextension and high posterior tibial slope (*Id*., ¶¶ 8, 9);
>
> (3) That Zimmer's warnings should have included a specific limitation on the amount of posterior tibial slope a patient should have after implantation of the N-K Flex (*Id*., ¶ 10);
>
> (4) That Plaintiff's failures as a result of her unique biomechanical condition, which caused posterior loading of her N-K Flex tibial articular surface, were foreseeable by Zimmer, and Zimmer should have warned of the risk of failure for her specific condition (*Id*., ¶ 11); and
>
> (5) That if Zimmer had warned of hyperextension and high posterior tibial slope or that the system was allegedly not tested for these conditions, he would not have used the product in Plaintiff, or her revision surgeries would have been avoided. (*Id*., ¶ 12.).

DE 95 at 2. The Defendants ask the Court to exclude the Affidavit and prevent Dr. Unis from testifying as an expert in this case.

In the Second Circuit, "a party's affidavit which contradicts his own prior deposition testimony should be disregarded on a motion for summary judgment." *Mack v. United States*, 814 F.2d 120, 124 (2d Cir. 1987) (collecting cases); *Raskin v. Wyatt Co.*, 125 F.3d 55, 63 (2d Cir. 1997). This is commonly referred to as a "sham affidavit." In the majority of sham affidavit cases, an affidavit is contradicted by prior deposition testimony. *See, e.g.*, *Raskin*, 125 F.3d at 63; *Ramos v. Baldor Specialty Foods, Inc.*, No. 10 Civ. 6271, 2011 WL 2565330, at *4 (S.D.N.Y. June 16, 2011). However, multiple district courts in this circuit have found the doctrine applicable when a party's subsequent deposition contradicts earlier non-deposition statements. *See, e.g.*, *U.S. Underwriters Ins. Co. v. 14-33/35 Astoria Blvd.*, No. 10-CV-1595, 2014 WL 1653199, at *6 (E.D.N.Y. Apr. 23, 2014) (citing the following cases as examples: *McCullough v. Burroughs*, No. 04-CV-3216, 2008 WL 2620123, at *4 (E.D.N.Y. June 30, 2008); *AB ex rel. EF v. Rhinebeck Cent. Sch. Dist.*, 361 F. Supp. 2d 312, 315-16 (S.D.N.Y. 2005)). *See also* 10B Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 2738, at 334–35 (3d ed. 1998) ("[A] witness' affidavit will not be automatically excluded because it conflicts with the witness' earlier or later deposition, despite the greater reliability usually attributed to the deposition. The court may, however, consider whether the conflict creates a credibility issue preventing summary judgment from being entered." (internal citations omitted)).

Further, the Third and Fifth Circuits have expressly ruled that the sham affidavit doctrine covers deposition testimony that contradicts an earlier affidavit. In *In re CitX Corp., Inc.*, 448 F.3d 672, 679-80 (3d Cir. 2006), the Third Circuit reasoned that they "perceive[d] no principle that cabins sham affidavits to a particular sequence[,]" and noted that cross-examining the affiant in a subsequent deposition is a more effective method of exposing a sham affidavit. *Id*. In *Hacienda Records, L.P. v. Ramos*, 718 F. App'x 223 (5th Cir. 2018) (summary order), the Fifth Circuit ruled

that as long as inconsistencies exist between the witness as a deponent and as an affiant, a district court is free to refuse to consider his statements, remarking that "[i]t is the competency, rather than timing, of evidence with which the sham-affidavit rule is concerned." *Id*. at 235. The reasoning of the Third and Fifth Circuits is adopted in this Case.

As noted above, Dr. Unis admitted in his second deposition that he did not write or edit the Affidavit. He did not review the package inserts associated with the Product or the surgical technique pamphlet prior to signing the Affidavit, despite the fact that the Affidavit explicitly states that he did so. Further, Dr. Unis acknowledged in his second deposition that the Affidavit contained multiple errors and inaccuracies. While Dr. Unis testified that he met with Plaintiff's counsel prior to signing the Affidavit, his acknowledgment that it contains inaccuracies contradicts any argument that he carefully reviewed the document before signing it.

Moreover, Dr. Unis either revised or contradicted his statements in all of the paragraphs the Defendants object to in the Affidavit.

1. Paragraph 7

Dr. Unis stated the following opinion in the Affidavit:

> I reviewed the Package Inserts associated with the Gender Solutions Natural-Knee Flex System, as well as the Gender Solutions Natural-Knee Flex System Surgical Technique Pamphlet, and find them to be **inadequate** because they provide a false sense of security to the treating surgeons. Specifically, I was unaware that the Gender Solutions Natural-Knee Flex System was **not** tested for patients with hyperextension or high posterior slope, and this is something that should have been disclosed.

Meyer Decl., Ex. A, ¶ 7 (emphasis in original). However, at his second deposition, Dr. Unis contradicted much of what he stated in this paragraph. First, as previously noted, he did not review either the package inserts or the surgical technique pamphlet prior to reading or signing the

Affidavit. Hence, he was unable to offer any opinion on their adequacy without knowing the content of these documents.

Further, although Dr. Unis testified that he did not know that the Product was not tested for patients with hyperextension or high posterior slope, he attested that "[he] do[es not] necessarily expect that [Zimmer] would have specifically tested patients [with hyperextension or high posterior slope]." Meyer Decl., Ex. B at 106:10-107:25. When asked by the Defendants' counsel if he expected Zimmer to test the Product in patients with hyperextension, Dr. Unis responded: "No. That's not how [medical device manufacturers] do it. I mean it's just, the question is not applicable. … [T]he bench testing is based on standards. … It's just the way it's done. They're not bringing patients in and testing them." *Id*. at 175:15-176:5. He was asked if he believed that Zimmer's testing was inadequate and replied that he did not believe so. *Id*. at 108:19-109:2. Rather, Dr. Unis stated that he is unaware of "anything that Zimmer failed to do in terms of researching this product or looking at [articular surface dislocation]." *Id*. at 115:1-6. If there were problems with the Product, Dr. Unis believed that they would be found in clinical data in national joint replacement registries. However, Dr. Unis testified that he is unaware of the existence of clinical data for any problems related to the Plaintiff. *Id*. at 108:22-109:5.

The Plaintiff contends that Dr. Unis relied upon Truman's opinions on the adequacy of Zimmer's testing in reaching his conclusions. However, this was contradicted by his testimony in his second deposition, where he admitted that he did not review Truman's expert report prior to signing the Affidavit. Moreover, Dr. Unis testified that his opinions were formed completely independent of those of Truman.

This testimony reveals that Dr. Unis does not hold the opinion that the Product should have been tested for patients with hyperextension or high posterior tibial slope. He did not read the

package inserts or surgical technique pamphlet to know if they were inadequate. As a result, he lacks a reliable basis to conclude that Zimmer should have disclosed the lack of testing in patients with hyperextension or high posterior tibial slope.

2. Paragraphs 8 and 9

Dr. Unis stated the following opinion in the Affidavit:

> There was no warning or contraindication listed in the Package Inserts that were in the Gender System for patients like Ms. WEBB who suffered from hyperextension and high posterior tibial slope. … In fact, prior to learning facts to the contrary in the lawsuit, I believed that Zimmer created this N-K 11 product specifically to match a patient's native tibial slope. If that was not the case, Zimmer had a duty to warn physicians and patients, or contraindicate the N-Ks use in patients with hyperextension and high posterior slope.

Meyer Decl., Ex. A, ¶¶ 8-9. In other words, Dr. Unis argues in his Affidavit that Zimmer had a duty to warn or contraindicate the Product for use in patients with hyperextension and high posterior slope.

However, during his second deposition, Dr. Unis recanted this opinion. Dr. Unis testified that hyperextension is not problematic and not an issue that requires a warning in the package insert. Meyer Decl., Ex. B at 48:12-20. In fact, he frequently chose not to correct patients' hyperextension during total knee replacements because leaving hyperextension "help[s] restore their natural kinematics," "feel[s] better to them" and "benefit[s] them." *Id*. at 46:13-47:20. When asked if Zimmer should have added a warning in the package insert instructing physicians not to put patients in hyperextension when performing total knee replacement with the Product, he replied that he "would not have been happy." *Id*. at 48:21-49:5. This sequence of testimony demonstrates that he did not believe, as his Affidavit states, that Zimmer should have included a warning for hyperextension.

Dr. Unis also testified that he had insufficient data to support a warning for hyperextension and high posterior tibial slope. He testified as follows:

> Q. But take it as a medical professional. If you're not aware of these two factors ever causing a failure by themselves in a patient, is there any evidence to support that a warning on just those two factors combined was necessary in the package insert?
>
> A. I don't have enough information about this type of failure in this implant, I just don't know.
>
> …
>
> Q. Given that you aren't aware of evidence of a problem of articular surface dissociation with the predecessor device or this device, you can't say that it was appropriate for there to be a warning against hyperextension and high posterior tibial slope, correct?
>
> A. That's true, that is true.

Id. at 68:17-69:2, 109:19-110:2. In his words, "if this was a real problem, where, you know, [the Product] w[as] failing because of [the combination of hyperextension and high posterior tibial slope], which, I don't have that information, then yes, I think a warning would be appropriate." *Id*. at 69:23-70. However, because he doesn't have the required information, he is unable to conclude that a warning is proper. *Id*. at 70:5-14 ("All I can say is that in this one case it failed.").

Dr. Unis lacks the reliable data required to support his opinion expressed in his Affidavit that a warning on hyperextension and posterior tibial slope was needed.

3. Paragraph 10

Dr. Unis stated the following opinion in the Affidavit:

> There is no doubt that Ms. WEBB' s natural posterior slope anatomy was at the higher range of normal, but there was nothing Zimmer prepared or circulated to state that it was still not within the realm of what Gender Solutions Natural-Knee Flex System could do because there was no warning stating the N-Ks limitation.

Meyer Decl., Ex. A, ¶ 10. While the surgical technique guide does warn surgeons to "avoid excessive posterior slope," in his Affidavit, Dr. Unis takes issue with the vagueness of that warning. Put differently, Zimmer should have provided a range of acceptable posterior tibial slope that a patient can have in the surgical technique guide.

However, Dr. Unis did not have sufficient information to draw this conclusion. In his second deposition, he acknowledged that he lacks the information required to conclude that any specific range or limitation on posterior tibial slope was appropriate for the Product's surgical technique guide. Specifically, he testified to the following:

> Q. You can't say based on the knowledge you have today that a specific limitation was appropriate here; is that correct?
>
> A. I just don't have the information to make that, that claim.
>
> Q. So that's correct then?
>
> A. I mean I would go back to what we were talking about before. If I – if there were, there if there was data out there, if there were incidents of failure that were picked up in national registries, et cetera, then I think that it's reasonable to put those warnings in. I don't have that information.
>
> Q. So without that information, you can't say that a specific limitation was necessary or appropriate?
>
> A. That's true.

Meyer Decl., Ex. B at 97:22-98:16. Dr. Unis testified that "excessive" posterior tibial slopes differ based on the patient's unique anatomy. *Id*. at 97:17-21.

As Dr. Unis does not have sufficient information to state that a specific limitation is appropriate and what that specific limitation may be, he is unable to state, with reasonable certainty, that Zimmer was required to provide a range of acceptable posterior tibial slope in the surgical technique guide.

4. Paragraph 11

Dr. Unis stated the following opinion in the Affidavit:

> Since the parties in this case agree that Ms. WEBB's biomechanical loading (i.e. excessive posterior loading) caused the failure of three N-K Flex Articular Surfaces, I state that Zimmer did not properly and adequately warn me that patients who have biomechanical loading like Ms. WEBB could be damaged and forced to undergo multiple surgeries because of a foreseeable N-K failure. This should have been in the warning Zimmer gave me with the product.

Meyer Decl., Ex. A, ¶ 11. In other words, Dr. Unis proffered the opinion that (1) the failures that occurred with the Product were foreseeable; and (2) he should have been warned about it.

First, Dr. Unis is unable to offer an opinion that allegedly inadequate warnings caused the Products failures in the Plaintiff, because he directly contradicted this in his second deposition. In pertinent part, he testified to the following:

> Q. Do you have the data and the information necessary to say that Zimmer's warnings were the cause of the revision surgeries here?
>
> A. That Zimmer's lack of warnings were the cause of the revisions?
>
> Q. Yes. Lack of warning or inadequacy.
>
> A. It is certainly one possibility.
>
> Q. It's a possibility, but you can't say that to a medical degree of certainty, correct?
>
> A. I guess that's how I would answer it. It is possible, but I – there are so many different factors with this woman that it would be impossible to really say.
>
> Q. So it's impossible to offer that opinion?
>
> A. Yes.

Meyer Decl., Ex. B at 163:18-164:14.

Correspondingly, he testified in his second deposition that he did not have enough information to testify that the failures that occurred in the Plaintiff's case were foreseeable. In pertinent part, he stated:

Q. There's a statement in here, I state that Zimmer did not properly and adequately warn me that patients who have biomechanical loading like Ms. Webb could be damaged and forced to go multiple surgeries because of a foreseeable N-K failure.

A. Yeah.

Q. Do you see a problem with that statement?

A. Not foreseeable. For one thing.

Q. Let me be clear. Are you saying that this was not foreseeable?

A. I don't know. I guess what I'm saying is I don't know if it was foreseeable because, again, I don't have that, the data. So I don't know.

Q. So is it fair to say that you don't have enough data to offer the opinions that Ms. Webb's biomechanical loading and her failures were foreseeable?

A. Yeah, I don't have that data, that's true.

Q. And because you don't have that data, you don't have that opinion, correct?

A. Yeah. I mean I did not foresee this, I can say that, if that answers your question. If I had foreseen this, I wouldn't have done the surgery.

Q. Is it fair to say that Zimmer couldn't have foreseen it either?

A. I don't know.

Q. Okay. But as a medical professional who's been implanting devices for over a decade, you acknowledge that the failure caused by her unique biomechanical loading was not foreseeable to you?

A. Yeah. I would -- based on what I know. Yeah.

Id. at 120:8-121:23. This amounts to a clear retraction of the opinion he offered in his Affidavit regarding foreseeability. Without having reliable information on the foreseeability of the failures of the Product in the Plaintiff, Dr. Unis is unable to conclude either that the failures were foreseeable or that a warning on the Plaintiff's biomechanical condition was necessary. To allow him to offer such an opinion at trial or in his Affidavit after he specifically recanted it in his deposition would be a clear violation of *Daubert* and its progeny.

5. Paragraph 12

Dr. Unis stated the following opinion in the Affidavit: "If Zimmer had properly warned or contraindicated the use of the Gender Solutions Natural-Knee Flex System by advising that it was not tested in patients with hyperextension or high posterior tibial slope, I would **not** have used it in Ms. WEBB." Meyer Decl., Ex. A, ¶ 12 (emphasis in original). As detailed *supra*, Dr. Unis did not testify that Zimmer's testing was insufficient or that a warning regarding hyperextension and high posterior tibial slope was necessary. In order for him to testify that he would not have used the Product in the Plaintiff's case if Zimmer had warned him that the Product was not tested in patients with hyperextension or high posterior tibial slope, Dr. Zimmer must believe that a warning was required. In pertinent part, he testified to the following:

> Q. … Is it fair to say that you're only saying that if there was a -problem that needed a warning, and a warning had been given and you'd seen the warning, then you would have not used it in Miss Webb?
>
> A. I think that's fair to say.
>
> Q. But you don't know, without evidence of whether there's a problem with articular surface dissociation, that a warning was appropriate?
>
> A. Yeah, that's true.

Meyer Decl., Ex. B at 114:8-18. This subsequent testimony clearly contradicts the premise of paragraph 12 of his Affidavit. As such, the Court concludes that Dr. Unis is precluded from offering this opinion to either create a disputed issue of fact in summary judgment or at trial.

The Defendants have demonstrated with reasonable certainty that Dr. Unis does not intend to provide testimony at trial consistent with his Affidavit. The Court's primary concern here is that "[i]f a party who has been examined at length on deposition could raise an issue of fact simply by submitting an affidavit contradicting his own prior testimony, this would greatly diminish the utility of summary judgment as a procedure for screening out sham issues of fact." *See Palazzo*

ex rel. Delmage v. Corio, 232 F.3d 38, 43 (2d Cir. 2000) (citing *Perma Research & Dev. Co. v. Singer Co.*, 410 F.2d 572, 578 (2d Cir. 1969)). The Plaintiff is not permitted to use an affidavit "that impeaches, without explanation, sworn testimony" to defeat summary judgment. *S.W.S. Erectors, Inc. v. Infax, Inc.*, 72 F.3d 489, 495 (5th Cir. 1996). The Court will not allow the Plaintiff to utilize the Unis Affidavit to escape summary judgment only to permit him to modify and contradict himself at trial. The Court holds that the statements in his Affidavit and in his second deposition are truly contradictory, *see Palazzo*, 232 F.3d at 43, and the second deposition explores these issues thoroughly. *Id*.

Accordingly, the Unis Affidavit will not be considered in the instant summary judgment motion. *See Palazzo*, 232 F.3d at 43 ("[A] party who has testified to a given fact in his deposition cannot create a triable issue merely by submitting his affidavit denying the fact." (internal citations omitted)). This document was manufactured for summary judgment. As such, the sham affidavit rule applies to the Unis Affidavit and the entire document is excluded.

Further, the opinions expressed in paragraphs seven through 12 in the Affidavit are not reflective of "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co.*, 526 U.S. at 152. These conclusions do not rest on a reliable foundation as Dr. Unis either admitted that he lacked sufficient information to draw such suppositions or contradicted the veracity of his claims. Accordingly, Dr. Unis is prohibited from testifying as an expert on these matters.

III. THE MOTION FOR SUMMARY JUDGMENT

A. STANDARD OF REVIEW

Pursuant to Rule 56, a "court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of

law." FED. R. CIV. P. 56(a); *see Tolbert v. Smith*, 790 F.3d 427, 434 (2d Cir. 2015); *Kwong v. Bloomberg*, 723 F.3d 160, 164-65 (2d Cir. 2013); *Holcomb v. Iona Coll.*, 521 F.3d 130, 137 (2d Cir. 2008). A dispute is genuine if the "evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 2510, 91 L. Ed. 2d 202 (1986).

It is the movant's burden to initially demonstrate the absence of material facts that preclude summary judgment. *See Huminski v. Corsones*, 396 F.3d 53, 69 (2d Cir. 2005) (citing *Castro v. United States*, 34 F.3d 106, 112 (2d Cir. 1994)). Such a "burden on the moving party may be discharged by 'showing' … that there is an absence of evidence to support the nonmoving party's case." *PepsiCo, Inc. v. CocaCola Co.*, 315 F.3d 101, 105 (2d Cir. 2002) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S. Ct. 2548, 2554, 91 L. Ed. 2d 265 (1986)).

If the movant meets the initial burden, the nonmoving party must present specific facts that demonstrate there is a genuine issue that should be left for the fact-finder to decide. *Davis v. New York*, 316 F.3d 93, 100 (2d Cir. 2002); *see also Matsuhita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986) (requiring the nonmoving party to "do more than simply show that there is some metaphysical doubt as to the material facts … the nonmoving party must come forward with 'specific facts showing that there is a genuine issue for trial.'" (internal citations omitted)). Mere conjecture, speculation, or conclusory statements are not enough to defeat summary judgment. *Kulak v. City of New York*, 88 F.3d 63, 71 (2d Cir. 1996) (internal citations omitted). The "mere existence of a scintilla of evidence" is insufficient to defeat summary judgment. *Anderson*, 477 U.S. at 252.

In considering a summary judgment motion pursuant to Rule 56, the Court must "view the evidence in the light most favorable to the non-moving party … and may grant summary judgment

only when 'no reasonable trier of fact could find in favor of the nonmoving party.'" *Allen v. Coughlin*, 64 F.3d 77, 79 (2d Cir. 1995) (internal citations omitted); *see also Doro v. Sheet Metal Workers' Int'l Ass'n*, 498 F.3d 152, 155 (2d Cir. 2007) (noting that in deciding a summary judgment motion, the court will "construe the evidence in the light most favorable to the nonmoving party and draw[] all inferences and resolv[e] all ambiguities in favor of the nonmoving party"); *Amnesty Am. v. Town of W. Hartford*, 361 F.3d 113, 122 (2d Cir. 2004) (stating that in deciding a Rule 56 motion, the court "is not to weigh the evidence but is instead required to view the evidence in the light most favorable to the party opposing summary judgment, to draw all reasonable inferences in favor of that party, and to eschew credibility assessments." (internal citations omitted)).

It is not the Court's responsibility to resolve any purported issues of disputed facts, but merely to "assess whether there are any factual issues to be tried, while resolving ambiguities and drawing reasonable inferences against the moving party." *Knight v. U.S. Fire Ins. Co.*, 804 F.2d 9, 11 (2d Cir. 1986) (internal citations omitted); *accord Cioffi v. Averill Park Cent. Sch. Dist. Bd. of Educ.*, 444 F.3d 158, 162 (2d Cir. 2006) (noting that the responsibility of the district court is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial" (quoting *Anderson*, 477 U.S. at 249)). "A genuine issue of fact for trial exists when there is sufficient evidence on which a jury could reasonably find for the plaintiff." *Cioffi*, 444 F.3d at 162 (quoting *Anderson*, 477 U.S. at 252).

B. FAILURE TO WARN

1. Adequacy of Zimmer's Warnings

Zimmer argues that its warnings are adequate as a matter of law and contends that the adequacy of these warnings is not a question of fact for a jury. Webb responds that there are

material issues of fact as to the adequacy of Zimmer's warnings. As explained below, the Court finds that the jury should make such a determination.

In New York State, to establish a *prima facie* case for failure to warn, a plaintiff must demonstrate that: (1) the manufacturer had a duty to warn; (2) the manufacturer breached that duty in a way that rendered the product defective; (3) the defect was a proximate cause of the plaintiff's injury; and (4) the plaintiff suffered damages. *See McCarthy v. Olin Corp.*, 119 F.3d 148, 156 (2d Cir. 1997) (citing *Becker v. Schwartz*, 46 N.Y.2d 401, 410, 386 N.E.2d 807 (1978)). These four elements are the same in New York, regardless of whether negligence or strict liability applies. *See Fane v. Zimmer, Inc.*, 927 F.2d 124, 130 (2d Cir. 1991) ("'Regardless of the descriptive terminology used to denominate the cause of action … where the theory of liability is failure to warn, negligence and strict liability are equivalent.'" (quoting *Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 62, 423 N.Y.S.2d 95 (4th Dep't 1979))). A manufacturer's duty to warn applies continuously and requires the manufacturer to keep abreast of the current safety information concerning its products. *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1345-46 (E.D.N.Y. 1992) (Spatt, J.).

In the context of medical devices, the duty to warn applies to a patient's physician, rather than to the patient, pursuant to the "learned intermediary" rule. *See Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993) ("[T]he duty to warn is owed to the medical community and, more specifically, to the treating physician who is to act as an 'informed intermediary' between the manufacturer and patient."); *Fane*, 927 F.2d at 129 ("[T]he physician's function is to evaluate a patient's needs, assess the risks and benefits of available [products] and then prescribe a [product], advising the patient of its risks and possible side effects." (quoting *Wolfgruber*, 72 A.D.2d at 62)). This duty applies "against latent dangers resulting from foreseeable uses of its

product of which it knew or should have known, [and] of the danger of unintended uses of a product provided these uses are reasonably foreseeable." *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237, 700 N.E.2d 203 (1998). "Liability for failure to warn may be imposed based upon either the complete failure to warn of a particular hazard or the inclusion of warnings that are insufficient." *Fisher v. Multiquip, Inc.*, 96 A.D.3d 1190, 949 N.Y.S.2d 214, 218 (3d Dep't 2012) (internal citations and quotation marks omitted).

New York law provides a defense against a failure to warn claim, if a drug or medical device is "properly prepared, and accompanied by proper directions and warning." *Martin v. Hacker*, 83 N.Y.2d 1, 8, 628 N.E.2d 1308 (1993) (internal citations and quotation marks omitted). To satisfy this duty, the manufacturer must "warn of all potential dangers in its prescription drugs [or devices] that it knew, or, in the exercise of reasonable care, should have known to exist." *Id*. Further, to be sufficient as a matter of law, it must provide "specific detailed information" regarding the risks of the product. *Id*. at 10. The warning is required to be "accurate, clear, consistent on its face, and [should] portray[] with sufficient intensity the risk involved in [using the device]." *Id*. In the context of medical devices, the manufacturer's duty is to the physician. To satisfy the duty to warn, the manufacturer is required to warn the physician by providing him or her sufficient information on the risks, rather than warning the consumer directly. *See Fane*, 927 F.2d at 129; *see also Martin*, 83 N.Y.2d at 9 ("The physician acts as an 'informed intermediary' [ ] between the manufacturer and the patient." (citing *Wolfgruber*, 72 A.D.2d at 61)).

As stated above, the package inserts for the Product do contain warnings for "[d]islocation," and "fracture/damage" in addition to warning that "[s]oft [t]issues should be balanced and components positioning confirmed to minimize edge loading." Zimmer argues that

these warnings are sufficient for summary judgment purposes and maintains that these warnings are adequate as a matter of law. The Court disagrees.

Although the Product did contain warnings concerning the risk of fracture and dislocation, "there are considerations that 'directly affect the adequacy of a warning, including the location and conspicuousness of the warning and the method in which the warning is communicated to the ultimate user.'" *In re Zimmer NexGen Knee Implant Prod. Liab. Litig.*, No. 11-cv-5468, 2017 WL 36406, at *12 (N.D. Ill. Jan. 3, 2017) (quoting *Figueroa v. Boston Sci. Corp.*, 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003)). In New York State, summary judgment is typically inappropriate where the adequacy of a warning may be considered questionable. *See Urena v. Biro Mfg. Co.*, 114 F.3d 359, 366 (2d Cir. 1997) ("'The adequacy of the instruction or warning is generally a question of fact to be determined at trial and is not ordinarily susceptible to the drastic remedy of summary judgment.'" (quoting *Beyrle v. Finneron*, 199 A.D.2d 1022, 1023 606 N.Y.S.2d 465 (4th Dep't 1993))); *see also Figueroa*, 254 F. Supp. 2d at 370 ("Generally, whether a warning is adequate is an issue of fact to be determined at trial."); *Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 440 (S.D.N.Y. 1999) (noting that the New York Court of Appeals describes failure to warn liability as fact-intensive).

Viewed in the light most favorable to the non-moving party, it is unclear that merely warning against fracture and dislocation, the effects of the Plaintiff's underlying conditions, is sufficient. As the Defendants themselves argue, the Plaintiff suffers from a variety of medical conditions that they allege contributed to the Product's ultimate failure. In the way the warnings are currently worded, there is significant ambiguity in whether Zimmer sufficiently warned surgeons of the causes of the facture and dislocation, including hyperextension, and whether or not they are foreseeable. A surgeon reading the Product's package inserts, which listed both

"fracture/damage" and "dislocation" as potential risks in the "Adverse Effects" section, may be unable to suitably understand the underlying causes or combination of causes that can cause fracture and dislocation. Further, the current warning does not contain the requisite specificity typically displayed in warnings that survive summary judgment. *See, e.g.*, *Maxwell v. Howmedica Osteonics Corp.*, 713 F. Supp. 2d 84, 95 (N.D.N.Y. 2010); *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284-85 (S.D.N.Y. 2009).

Truman opines in her expert report that the package insert was misleading, vague, and incomplete, especially with the underlying conditions that plagued the Plaintiff. *See* Declaration of Joseph T. Pareres ("Pareres Decl."), DE 107, Ex. A at 41. A jury may reasonably conclude that a warning of fracture and dislocation in addition to advising surgeons that "[s]oft [t]issues should be balanced and components positioning confirmed to minimize edge loading" are insufficient to satisfy the duty to warn.

New York State also recognizes that a "manufacturer has a duty to warn against latent dangers resulting from foreseeable users of its product of which it knew or should have known." *In re New York City Asbestos Litig.*, 27 N.Y.3d 765, 788, 59 N.E.3d 458 (2016); *see also* Restatement (Third) of Torts: Prod. Liab. § 2 (1998) ("[The] seller bears responsibility to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal … [a] seller is charged with knowledge of what reasonable testing would reveal.").

In the instant case, the Plaintiff has procured evidence that Zimmer should have known that at least one of the Plaintiff's conditions was foreseeable and that the Defendants did not test or monitor for the Plaintiff's underlying conditions. *See Krasnopolsky*, 799 F. Supp. at 1347 ("In response to a summary judgment motion, a plaintiff must come forward with evidentiary facts

which tend to show that the manufacturer's warnings were deficient."). Viewed in the light most favorable to the non-moving party, it is plausible for a jury to conclude that Zimmer failed to conduct testing on foreseeable risks of the Product and that Zimmer failed to warn about its lack of testing of that risk.

2. Causation

Having found that there are sufficient factual questions to preclude summary judgment as to whether Zimmer satisfied its duty to warn, the Court must then proceed to examine whether the alleged inadequacy of the Products warnings was the proximate cause of the Plaintiff's injuries. *See Glucksman v. Halsey Drug Co.*, 160 A.D.2d 305, 307, 553 N.Y.S.2d 724 (1st Dep't 1990). The Defendants contend that (1) the Plaintiff did not show that if the Defendants had provided the proposed warning, that it would have prevented the Plaintiff's injuries; (2) that the Plaintiff's factors were unique and unforeseeable; and (3) that the treating physician, Dr. Unis, already knew of the risk of fracture and dislocation. The Court finds that the first argument is dispositive.

The Plaintiff must demonstrate that had a different warning been used, Dr. Unis would not have surgically implanted the Product in Webb. *Id.; see also In re Zyprexa Prods. Liab. Litig.*, 649 F. Supp. 2d 18, 33 (E.D.N.Y. 2009) (holding that the Plaintiff failed to meet its burden establishing that the inadequate warning caused the prescribing physician to alter his decision to prescribe the drug in question); *Alston*, 670 F. Supp. 2d at 285 ("[The] plaintiff must demonstrate that had a different, more accurate warnings been given, his physician would not have prescribed the drug [or medical device] in the same manner."). If the Plaintiff fails to raise a genuine issue of material fact regarding whether Dr. Unis would have prescribed a different device for a total knee replacement, summary judgment is appropriate.

The Plaintiff has not introduced sufficient evidence to meet this burden. This Court has already precluded the Unis Affidavit and ruled that it may not be used for the purposes of deciding the instant motion for summary judgment. The record reflects that Dr. Unis chose to use the Product for all his primary implants based on his comfort with the Product rather than any of Zimmer's marketing materials or warnings contained in the package inserts. *See* DE 63-4 at 44:18-45:12 ("I was using [the Product] for all of my primaries. … I was comfortable with the nuances of th[e Product] which I think contributes to the success of putting in an implant[.] … [Y]ou are better off having the surgeon be comfortable with whatever system that he or she uses than having that surgeon use whatever is the latest, greatest thing being marketed."). There is therefore little basis for believing and no evidence concluding that had Zimmer's warnings been different, Dr. Unis would have chosen a different implant for Webb.

This is corroborated by his history, as Dr. Unis continued to use the Product for his primary knee replacements through 2014, long after the Plaintiff was forced to undergo multiple revision surgeries. *Id*. at 46:18-20. To this day, Dr. Unis remains confident in the product. *Id*. at 46:3-4. Also, the Plaintiff has provided no evidence that she was directly involved in the choice of implant nor that a strengthened warning would have caused her to opt-out of the surgery.

Notwithstanding the Plaintiff's contentions, the findings contained in Truman's expert report do not alter this result. Truman merely equivocates that "[Dr. Unis] may have used a different style implant" had he had "sufficient information." DE 78-1 at 42. The portions of the Truman report cited by the Plaintiff falls short of the evidence required to create a triable issue of fact as they are contradicted by the testimony of the Plaintiff's treating physician. In addition, Truman's opinions that Zimmer's failure to contraindicate or provide "sufficient information" to Dr. Unis caused the Plaintiff's injuries "is unsubstantiated and therefore fails to create a genuine

issue of material fact." *Kline v. Zimmer Holdings, Inc.*, 662 F. App'x 121, 126 (3d Cir. 2016) (summary order). Dr. Unis was using the Product for all of his primary knee replacements, regardless of the circumstances of the individual patient, and was doing so based on his comfort with the Product. The Plaintiff has to show that had the warning on the Product been different, Dr. Unis would have taken that into consideration, and departed from exclusively using the Product. The Plaintiff failed to put forth any evidence that this would be the case, and as a result, summary judgment is appropriate.

As the Court has already determined that summary judgment is appropriate, the Court declines to address the Defendants' remaining arguments in support of summary judgment regarding the Plaintiff's failure to warn claims.

C. PUNITIVE DAMAGES

Having found that summary judgment is appropriate on the Plaintiff's failure to warn claims, the Plaintiff's punitive damages claim is also dismissed. However, as both parties addressed the merits of punitive damages in their respective briefs, the Court will address punitive damages in the instant case. Webb argues that the Defendants have acted with "reckless disregard in that they failed to warn treating physicians … that Zimmer failed to conduct studies to determine the increased risk of failure of the N-K Flex product in individuals with hyperextension." DE 108 at 26.

"[U]nder New York law, punitive damages are not a separate cause of action," but they are "inextricably linked to the underlying cause of action." *Greenbaum v. Svenska Handelsbanken, N.Y.*, 979 F. Supp. 973, 982 (S.D.N.Y. 1997) *on reconsideration sub nom*. *Greenbaum v. Handelsbanken*, 26 F. Supp. 2d 649 (S.D.N.Y. 1998); *Rocanova v. Equitable Life Assur. Soc. of U.S.*, 83 N.Y.2d 603, 616, 634 N.E.2d 940 (1994) ("A demand or request for punitive damages is

parasitic and possesses no viability absent its attachment to a substantive cause of action[.]"); *Kurtz v. Lelchuk*, 2006 WL 1982598, at *10, 12 Misc.3d 1182(A) (N.Y. Sup. Ct. 2006) ("New York does not recognize a separate cause of action for punitive damages."). As the Court has dismissed the Plaintiff's underlying substantive failure to warn claims, the Defendants are entitled to summary judgment as to the related punitive damage claim.

However, regardless of the Court's decision as to the underlying merits of the failure to warn claims, the Plaintiff is unable to maintain her punitive damages claim. Punitive damages may be awarded when a defendant acts with a "high degree of moral culpability which manifests a conscious disregard for the rights of others or conduct so reckless as to amount to such disregard." *Home Ins. Co. v. Am. Home Prod. Corp.*, 75 N.Y.2d 196, 203, 550 N.E.2d 930 (1990) (internal citations and quotation marks omitted). Construing all evidence in the light most favorable to the Plaintiff and drawing all reasonable inferences in the Plaintiff's favor, the Plaintiff has offered no evidence that the Zimmer's conduct exceeds ordinary negligence. *Ross v. Louise Wise Servs., Inc.*, 8 N.Y.3d 478, 489, 868 N.E.2d 189 (2007) ("Punitive damages are permitted when the defendant's wrongdoing is not simply intentional but evince[s] a high degree of moral turpitude and demonstrate[s] such wanton dishonesty as to imply a criminal indifference to civil obligations. ... The misconduct must be exceptional, as when the wrongdoer has acted maliciously, wantonly, or with a recklessness that betokens an improper motive or vindictiveness ... or has engaged in outrageous or oppressive intentional misconduct or with reckless or wanton disregard of safety or rights." (internal citations and quotation marks omitted)).

Accordingly, the Defendants' motion for summary judgment as it pertains to the Plaintiff's punitive damages claim is granted.

D. CLAIMS AGAINST ZIMMER BIOMET HOLDINGS, INC. & ZIMMER SURGICAL, INC.

The Defendants assert in their summary judgment papers that the Court should grant summary judgment as to Zimmer Biomet Holdings, Inc. and Zimmer Surgical, Inc. due to a lack of evidence to hold them liable for the Plaintiff's failure to warn claim. As the Court has already dismissed the Plaintiff's failure to warn claims, this finding is applicable to all the Defendants, including Zimmer Biomet Holdings, Inc. and Zimmer Surgical, Inc.

Nevertheless, even if the Defendants were not entitled to summary judgment on the failure to warn claims, Zimmer Biomet Holdings, Inc. and Zimmer Surgical, Inc. must be dismissed due to the Plaintiff's failure to address the Defendants' arguments in her summary judgment papers.

In the Second Circuit, a party that fails to raise an argument in its opposition papers in a motion for summary judgment has waived that argument. *Triodetic Inc. v. Statue of Liberty IV, LLC*, 582 F. App'x 39, 40 (2d Cir. 2014) (summary order) ("[P]laintiff never raised these arguments in its opposition to defendants' motion for summary judgment. Accordingly, these arguments were waived."); *Aiello v. Stamford Hosp.*, 487 F. App'x 677, 678 (2d Cir. 2012) (summary order) ("The premise of our adversarial system is that courts do not sit as self-directed boards of legal inquiry and research, but essentially as arbiters of legal questions presented and argument by the parties before them." (internal citations omitted)); *Palmieri v. Lynch*, 392 F.3d 73, 87 (2d Cir. 2004) ("[The plaintiff] failed to … raise this argument in his opposition to summary judgment. Thus, this argument has been waived."); *NML Capital, Ltd. v. Republic of Argentina*, No. 05-cv-2434, 2009 WL 1528535, at *1 (S.D.N.Y. May 29, 2009) (holding that the plaintiffs were entitled to summary judgment on an issue because the defendant waived the argument by failing to raise it in its opposition to the plaintiffs' summary judgment motion).

In the instant case, the Defendants address their arguments pertaining to Zimmer Biomet Holdings, Inc. and Zimmer Surgical, Inc. in their memorandum in support of their summary

judgment motion. *See* DE 100 at 22-23. The Plaintiff failed to address these arguments at any point in her summary judgment opposition briefing. *See* DE 108. Thus, the Plaintiff has waived these arguments and the Defendants are entitled to summary judgment on all claims as they relate to Zimmer Biomet Holdings, Inc. and Zimmer Surgical, Inc.

IV. CONCLUSION

For the reasons set forth above, the Defendants' motion to strike the Unis Affidavit is granted. Paragraphs seven through 12 of the Unis Affidavit are stricken from the record and Dr. Unis is prohibited from testifying as an expert in those matters.

Further, the Defendants' motion for summary judgment pursuant to Rule 56 dismissing all of the Plaintiff's claims is granted. The Clerk of the Court is respectfully directed to close the case.

It is **SO ORDERED**:

Dated: Central Islip, New York
February 4, 2019

/s/ Arthur D. Spatt
ARTHUR D. SPATT
United States District Judge